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The Necessity of Sterile Gloves for the Closure of Simple Lacerations

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The Necessity of Sterile Gloves for the Closure of Simple Lacerations

Abstract

Background: Lacerations are a common presenting complaint in the acute care setting. Current guidelines recommend the use of sterile technique for the exploration and closure of these wounds in order to reduce the risk of subsequent infection. Research in other medical specialties has cast doubt on the effectiveness of sterile gloves in lowering infection rates for uncomplicated procedures. The use of sterile surgical gloves is associated with increased costs in materials, labor, and time. This review hopes to answer the question: are sterile gloves necessary for the closure of simple lacerations?

Methods: Exhaustive search of available medical literature was performed. Ovid MEDLINE, Web of Science, Cinahl, and Google Scholar were used to obtain articles relevant to the question being asked. Articles were critically appraised and included in the systematic review if they met predefined inclusion criteria.

Results: Four randomized controlled trials were included in this review. None of these studies showed a statistically significant decrease in wound infections when comparing sterile gloves to an alternative clean approach for the closure of simple lacerations.

Conclusion: For patients with no significant risk factors, we can be moderately confident that sterile gloves do not decrease the incidence of wound infections after simple laceration repair. The available evidence does not show a benefit justifying the higher cost associated with their use. Further research is necessary to strengthen the confidence of the recommendation.

Keywords: *lacerations; wound infection; humans; gloves, surgical*

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lacerations, wound infection, humans, gloves, surgical

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The Necessity of Sterile Gloves for the Closure of Simple Lacerations

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A Clinical Graduate Project Submitted to the Faculty of the

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Biography

[Redacted for privacy]

Abstract

Background: Lacerations are a common presenting complaint in the acute care setting. Current guidelines recommend the use of sterile technique for the exploration and closure of these wounds in order to reduce the risk of subsequent infection. Research in other medical specialties has cast doubt on the effectiveness of sterile gloves in lowering infection rates for uncomplicated procedures. The use of sterile surgical gloves is associated with increased costs in materials, labor, and time. This review hopes to answer the question: are sterile gloves necessary for the closure of simple lacerations?

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Conclusion: For patients with no significant risk factors, we can be moderately confident that sterile gloves do not decrease the incidence of wound infections after simple laceration repair. The available evidence does not show a benefit justifying the higher cost associated with their use. Further research is necessary to strengthen the confidence of the recommendation.

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List of Abbreviations

ED.....	Emergency Department
NNH.....	Number Needed to Harm
NNT.....	Number Needed to Treat

The Necessity of Sterile Gloves for the Closure of Simple Lacerations

BACKGROUND

Superficial lacerations are one of the most common presenting complaints in the acute care setting. Emergency Departments alone manage 12.2 million of these wounds annually.¹ The majority of these patients will have no significant morbidity associated with their injury. However, wound infection is the most common complication in the management of lacerations.² Infected lacerations are more likely to result in poor cosmetic outcomes and may need further scar revision.^{2,3} Therefore it becomes one of the primary goals of laceration management to prevent secondary wound infection.²

Certain characteristics of the wound may make it more prone to infection. These risk factors include increasing patient age, personal history of diabetes mellitus, wound contamination, and the size and location of the wound.^{3,4} Additional complications at the time of injury may include neurovascular compromise, tendon injury, retained foreign body, or fracture.² If all of these risk factors or complications are absent, the laceration may be called simple or uncomplicated.

In an effort to minimize the risk of infection, regardless of risk factors, it has become common practice to adhere to strict sterile techniques while performing the closure. This often involves the use of sterile saline for irrigation, sterile materials and instruments, and the donning of surgical gloves.

The questioning of strict sterile technique for simple laceration repair is nothing new. A recent meta-analysis showed that there was no increased risk for infection when comparing tap water to normal saline for the cleansing of uncomplicated traumatic wounds.⁵ And though current guidelines still recommend the use of sterile surgical gloves for the closure of lacerations,⁶ no systematic review has been conducted showing the efficacy of this in lowering infection rates.

The sterility of the gloves themselves has become a topic of research. For a wound to become infected, $>10^5$ organisms/mL are required at the source.⁷ Sterile gloves have been shown to carry less of a bacterial load than clean non-sterile gloves. However, cultures obtained from clean gloves have not shown the requisite number of colony forming units needed for an infection to form.⁸ There is also no evidence that the bacterial loads on clean gloves in a nearly empty box significantly differ from those in a recently opened container.⁹

Because the use of sterile gloves increases cost in materials and time, there should be evidence supporting its utility in lowering post-closure infection rates. Therefore the question can be asked: are sterile gloves necessary for the closure of simple lacerations?

METHODS

An exhaustive search of the medical literature was performed using Ovid MEDLINE, Web of Science, Cinahl, and Google Scholar. Keywords included:

lacerations; wounds, nonpenetrating; wound infection; asepsis; sterilization; antisepsis; sterile technique; gloves. Critically appraised articles were limited to prospective randomized controlled trials on human subjects in the English language. Dental procedures and elective surgical operations were excluded from the review. Bibliographies of critically appraised articles were combed for relevant additional information. The quality of evidence presented by the included studies was assessed using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) system.¹⁰

RESULTS

The search retrieved 24 abstracts that were screened, and of these 12 full text articles were assessed for eligibility (Figure 1). A total of four randomized controlled trials were selected to be included in the systematic review based on the predefined inclusion/exclusion criteria.¹¹⁻¹⁴ See Table I.

Perelman et al

This was a prospective, blinded, randomized controlled trial¹¹ conducted in 2004 at three community hospitals in a major metropolitan Canadian city. The investigators examined whether non-sterile gloves lead to an increased rate of wound infection during the closure of uncomplicated lacerations in immunocompetent patients. The primary endpoint was defined as an infection at time of follow up requiring antibiotics or referral.¹¹

Inclusion criteria was determined to be any patient over 1 year of age who presented to the Emergency Department with an uncomplicated laceration. Patients were excluded if they had a medical history predisposing them to an increased risk of wound infection, including but not limited to diabetes, asplenia, or renal failure. Patients currently taking antibiotics were also excluded. Uncomplicated wounds were defined as those being absent of confounding factors, such as neurovascular or tendon injury, bites, penetrating trauma, or retained foreign bodies.¹¹

Randomization was achieved through a specially designed randomization table and patients were allocated via block-randomization in blocks of 60 with further stratification based on laceration site. This was done secondary to the increased risk of infection based on anatomic location of the wound.²⁻⁴ A total of 816 patients were randomized to receive either standard intervention with sterile gloves ($n=408$) or experimental intervention with clean non-sterile gloves ($n=408$). The two groups were similar in terms of prognostic variables and demographic characteristics at baseline. Repair technique and materials used varied from provider to provider, but overall characteristics between the control and experimental groups were similar.¹¹

The provider performing the closure was not blinded to patient allocation. Blinding of the patient was achieved through application of the gloves outside of the room, prior to the procedure. The follow-up provider who determined wound infection, was also blinded to group allocation.¹¹

The study was not prematurely stopped and patients were analyzed in the groups in which they were initially allocated. Overall loss to follow up was insignificant ($n=6$ in sterile group, $n=12$ in clean glove group).¹¹

Clinically significant infection was the primary endpoint of interest. The infection rate in the clean gloves group was 4.4% (17 patients; 95% CI 2.4% to 6.4%) and 6.1% in the sterile gloves group (24 patients; 95% CI 3.8% to 8.4%). These differences were not statistically significant (relative risk 1.39; 95% CI 0.76 to 2.55; NNH 60; 95% CI 21 to -69). The characteristics of the infections were similar across the two groups, with neither group exhibiting a statistically significant need for parenteral antibiotics.¹¹ See Table II.

The authors self-identified limitations in their study design. These included the lack of complete blinding and absence of repair technique standardization. They also mention the possibility that providers using non-sterile clean gloves were more aware of contamination during the procedure, leading them to prepare and cleanse the wound more aggressively. This was unlikely to have occurred, due to the similarity in the reported rates of wound irrigation, preparatory solution use, and repair technique between the two groups. The authors conclude that clean non-sterile gloves are appropriate for the closure of simple uncomplicated lacerations.¹¹

Maitra et al

Though this prospective randomized controlled trial¹² focused solely on hand lacerations, its results were relevant to the clinical question being asked.

The study was conducted in 1986, and the authors examined wound infection rates in sutured hand lacerations, comparing the use of sterile gloves versus no gloves.¹²

Patients were included in the study if they were over 16 years of age and not receiving antibiotics, steroids, or immunosuppressive drugs. Lacerations were less than 5 cm long, only involving the skin and subcutaneous tissue, no more than 4 hours from injury, and not excessively contused. Group allocation was randomized for 230 patients with 242 wounds through the drawing of randomized cards marked “gloves” or “no gloves.” The follow-up provider was blinded to allocation at the time of assessment. The two groups were similar in regards to distribution of age, sex, and site of wound. No other prognostic characteristics were defined.¹²

The repair technique was standardized between the two groups, with the only difference being application of sterile gloves. Wound preparation was performed with aqueous chlorhexidine and the provider, regardless of glove use, performed surgical scrub with chlorhexidine gluconate.¹²

Infections were reported based on time since repair and degree of infection. In the sterile glove group, 18 of the 121 wounds became infected (14.9%). These were equally distributed between early infections (48 hours after closure) and late infections (occurring 8 days after closure). The majority of the infections in the sterile glove group were labeled a Grade I infection ($n=12$), defined as less than 1 cm of erythema from the suture line. Five wounds were

labeled Grade II (greater than 1 cm of erythema from suture line), and one wound was Grade III (Grade I or II plus purulence). For the 121 wounds closed with no gloves, 17 went on to form infections (14.0%). There were nine Grade I infections, two Grade II infections, and six Grade III infections. There was no statistically significant difference in total infections between the two groups (relative risk 1.05; 95% CI 0.57 to 1.96; NNH 121; 95% CI 10 to -12). There were five late Group III infections in the no-glove group, compared to 0 in the sterile glove group. Which represents a statistically significant difference ($p < 0.01$). The authors conclude that this data supports the use of sterile gloves for prevention of late purulent infection in the closure of hand lacerations.¹²

Worrall

This small, prospective, randomized controlled trial¹³ was performed by a single general practitioner in a rural community in 1989. The clinical outcome of importance was infection rates in uncomplicated lacerations after closure with full sterile technique versus a surgically-clean approach.¹³

Patients were excluded from the study if their wounds involved tissues other than the skin or subcutaneous fat, were grossly contaminated, had delayed presentation (greater than 6 hours from time of injury), or needed general anesthesia for the procedure.¹³

The author randomized patients by placing an equal number of colored beads in an opaque bag. If a yellow bead was drawn, the patient was allocated to the sterile group. If a red bead was drawn, the patient received a surgically clean

procedure. A total of 50 participants were selected, with an equal number of patients divided between the two groups. There is no explicit comparison of prognostic variables or demographic characteristics between the two groups.¹³

Sterile technique involved irrigation with sterile saline; application of sterile facemask, gloves, and gown; and draping the wound with sterile towels prior to closure. The surgically clean procedure was performed after the provider washed his hands with soap and water and irrigated the wound with tap water. Mask, gloves, and drapes were not used during the clean closure. Secondary to the study design, no blinding was conducted.¹³

Wounds were assessed for infection 2-3 days after closure and at the time of suture removal. The author performed the wound assessment. Twenty-two of the 25 patients in the sterile group (88%), and 21 of the twenty-five patients in the clean group (84%) returned for follow-up. Clinical infections were present in three of the patients in the clean group and 10 of the patients in the sterile group.¹³ These results are statistically significant (relative risk 3.18; 95% CI 1.01 to 9.98; NNH 4; 95% CI 2 to 27).

Worrall recognizes the lack of blinding in his study design, but concludes that using clean technique is acceptable for the closure of uncontaminated, simple skin lacerations.¹³

Bodiwala et al

This prospective randomized trial¹⁴ also compared infection rates in wounds repaired with or without sterile gloves in the accident-and-emergency department of a university hospital in the UK in 1982.

Patients were randomized at time of intake to have their lacerations repaired using sterile surgical gloves or no gloves. Demographic characteristics were not provided and no blinding took place. Data was collected on a total of 418 wounds, with follow up reported for 408 wounds. The group allocation for the lost to follow up is not included in the study.¹⁴

Wound infections were defined as severe if there was presence of purulence or dehiscence and classified as mild if there was any erythema or serous drainage. Rates of infection in the group that had no gloves used was 17.5% ($n=35$), with 75% of those being mild ($n=27$) and 25% being severe ($n=9$). In the group that had closure performed with sterile gloves, 17.3% of wounds become infected ($n=35$), 77.1% ($n=27$) were mild and 22.9% ($n=8$) severe. There was no statistically significant difference in total infection rates between the two groups (relative risk 0.99; 95% CI 0.65 to 1.51; NNT 672; 95% CI 13 to -14). The comparison also failed to show any statistically significant risk of severe infection (relative risk 0.91; 95% CI 0.36 to 2.3; NNT 245; 95% CI 22 to -26).¹⁴

DISCUSSION

Current guidelines continue to recommend the use of sterile technique for the closure and exploration of all lacerations.^{2,6} However, there has been no

systematic review or meta-analysis to confirm that adhering to strict sterile technique during wound closure lowers the rate of wound infection. A review of the available medical literature¹¹⁻¹⁴ suggests that for uncomplicated lacerations, sterile gloves do not significantly lower the incidence of site infection. See Table II.

The studies reviewed were not without their limitations. Perelman et al¹¹ had the largest sample size of the appraised trials ($n=816$), but lacked any standardized method for wound closure. This may have increased the number of confounding factors that could influence the final results. However, the authors included the characteristics of the laceration repairs showing no significant differences between the two groups.

Maitra et al¹² allocated patients by drawing a randomized card, which was then thrown away. This strategy may have achieved randomization, but the methodology lends itself to potential bias.

Though patients were randomized, the Worrall study¹³ was methodologically flawed secondary to his lack of blinding and significantly high loss to follow up (12% in the sterile group, 16% in the clean group). The risk of bias increases when one provider chooses group allocation, sutures the wound, and then determines the presence of infection. His small sample size ($n=50$) also decreases the precision of his results.

Bodiwala et al¹⁴ failed to identify and match groups based on prognostic variables and patient demographics at time of allocation. The lack of knowledge

of these group characteristics increases the risk of inconsistencies in the results. The study also examined other risk factors significant for wound infection, but did not account for these in their initial group allocation. Randomization was achieved through the drawing of a packet that indicated whether the laceration was to be repaired with or without sterile gloves. Nonetheless, it was not revealed how these packets were randomized.

In spite of these limitations, the evidence suggests that clinicians can be moderately confident that using sterile gloves, for the closure of an uncomplicated laceration, will not lower the incidence of wound infection. Before an alternative clean technique can be used, the patient and laceration must first be stratified by risk of infection. High-risk patients include those with a history of diabetes mellitus, peripheral vascular disease, chronic renal failure, asplenia, malnutrition, or the use of immunosuppressive drugs.²⁻⁴ A laceration that is heavily contaminated; greater than 5cm long; involves damage to tendons, nerves, or vasculature; or is associated with a fracture is also at a greater risk for complication.²⁻⁴

Maintaining strict sterile technique has been questioned in specialties outside of the emergency setting.¹⁵⁻²² Multiple studies in the field of dermatology have shown that using sterile gloves during Mohs micrographic surgery does not significantly lower the incidence of post-op infection.¹⁵⁻¹⁷ In a study whose results may be applied to the closure of simple traumatic lacerations, Rogues et al²² found that for simple excisions (<2 cm) with sutures, the use sterile gloves

did not significantly lower the rate of surgical site infections (1.6% with sterile gloves, 1.7% without).

In an era of maximizing cost savings, the difference between sterile and clean techniques has consequential financial outcomes. From the standpoint of labor, using sterile gloves may necessitate the presence of an additional assistant to minimize the risk of sterile-field violations. In terms of materials, sterile gloves cost US\$0.70 per pair versus clean, non-sterile examination gloves, which cost US\$0.10 per pair.¹¹ If one considers the millions of lacerations performed annually,¹ this US\$0.60 difference equates to a real economic impact. The extra time needed to perform a sterile procedure may also affect the workflow of a busy ED. This has the potential to diminish patient satisfaction and may ultimately lead to a lower quality of care provided.^{23,24}

CONCLUSION

Despite the limitations of the reviewed studies, the available evidence points to the conclusion that clinicians can be moderately confident that sterile gloves do not significantly decrease the incidence of infection in the closure of simple lacerations. When a patient presents with this traumatic injury, they must be stratified based on the presence or absence of previously defined risk factors. For patients with low risk injuries, the evidence suggests that a clean, non-sterile approach would be appropriate for the management of the wound. Future

studies with sound methodologies are needed to increase the confidence of this recommendation.

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Table I. Characteristics of Reviewed Studies

Quality Assessment							
		Downgrade Criteria					
Study	Design	Limitations of Methodology	Indirectness	Imprecision	Inconsistency	Publication bias likely	Quality
Perelman et al ¹¹	Randomized Controlled Trial	No serious limitations	No serious indirectness	No serious imprecision	No serious inconsistencies	No bias likely	High
Maitra et al ¹²	Randomized Controlled Trial	Serious limitations ^a	No serious indirectness	No serious imprecision	No serious inconsistencies	No bias likely	Moderate
Worrall ¹³	Randomized Controlled Trial	Very serious limitations ^a	No serious indirectness	Serious imprecision ^b	No serious inconsistencies	No bias likely	Very Low
Bodiwala et al ¹⁴	Randomized Controlled Trial	Serious limitations ^a	No serious indirectness	No serious imprecision	Very serious inconsistencies ^c	No bias likely	Very Low

^aMaitra et al¹² randomized group allocation in their study, but lacked a strong methodology for doing so. Worrall's study¹³ suffered from significant loss to follow up and a methodologically weak blinding design. In Bodiwala et al's trial¹⁴ group allocation was randomized, but no description of the method was given.

^bWorrall¹³ had a small sample size ($n=50$) for his RCT.

^cBodiwala et al¹⁴ failed to identify prognostic variables between the two groups that may have increased the risk of infection.

Table II. Summary of Findings

Summary of Findings				
Study	Number of Patients with Infected Wounds		Effect	
	Sterile Gloves	Non-sterile Technique	Relative Risk (95% CI)	NNT/NNH (95% CI)
Perelman et al ¹¹	24/402	17/396	1.39 (0.76 to 2.55)	NNH: 60 (21 to -69)
Maitra et al ¹²	18/121	17/121	1.06 (0.57 to 1.96)	NNH: 121 (10 to -12)
Worrall ¹³	10/22	3/21	3.18 (1.01 to 9.98)	NNH: 4 (2 to 27)
Bodiwala et al ¹⁴	35/202	36/206	0.99 (0.65 to 1.51)	NNT: 672 (13 to -14)

Figure I. PRISMA 2009 Flow Diagram

